

RECEIVED  
CENTRAL FAX CENTER

3 APR 02 2007 Docket No. UF-270C3  
Serial No. 10/588,749

In the Claims

1-56 (canceled).

57 (original). A method of monitoring a patient during administration of at least one therapeutic drug, said method comprising:

administering to the patient at least one therapeutic drug;

exposing at least one sensor to expired gases from the patient;

detecting one or more target markers from the therapeutic drug with said sensor.

58 (original). The method of claim 57 wherein said target marker is the therapeutic drug.

59 (original). The method of claim 57 wherein said target marker is a metabolite of the therapeutic drug indicative of the therapeutic drug.

60 (original). The method of claim 57 wherein said target marker is selected from a group consisting of dimethyl sulfoxide (DMSO), acetaldehyde, acetophenone, trans-Anethole (1-methoxy-4-propenyl benzene) (anise), benzaldehyde (benzoic aldehyde), benzyl alcohol, benzyl cinnamate, cadinene, camphene, camphor, cinnamaldehyde (3-phenylpropenal), garlic, citronellal, cresol, cyclohexane, eucalyptol, and eugenol, eugenyl methyl ether; butyl isobutyrate (n-butyl 2, methyl propanoate) (pineapple); citral (2-trans-3,7-dimethyl-2,6-heptadiene-1-al); menthol (*t*-methyl-4-isopropylcyclohexane-3-ol); and  $\alpha$ -Pinene (2,6,6-trimethylbicyclo-(3,1,1)-2-heptene).

61 (original). The method of claim 57 wherein at least one therapeutic drug is administered to the patient orally.

62 (original). The method of claim 57 wherein at least one therapeutic drug is delivered intravenously.

63 (original). The method of claim 57 wherein the detecting step comprises detecting both presence and concentration of the target marker to determine at least one therapeutic drug concentration in blood.

64 (original). The method of claim 63 further comprising assigning a numerical value to the concentration as analyzed upon reaching a level of therapeutic effect of said therapeutic drug in said patient and, thereafter, assigning higher or lower values to the concentration based on its relative changes.

65 (original). The method of claim 64, further comprising monitoring the concentration by monitoring changes in said value and adjusting administration of the therapeutic drug to maintain a desired therapeutic effect.

66 (original). The method of claim 63 further comprising determining an appropriate dosage of at least one therapeutic drug based on the concentration of at least one target marker detected in said expired gases.

67 (original). The method of claim 57 wherein the steps are repeated periodically to monitor pharmacodynamics and pharmacokinetics of at least one therapeutic drug over time.

68 (original). The method of claim 57 wherein at least one therapeutic drug is for depression.

69 (original). The method of claim 57 wherein at least one therapeutic drug is for analgesia.

70 (original). The method of claim 57 wherein at least one therapeutic drug is selected for the treatment of a condition selected from group consisting of rheumatoid arthritis, systemic

JAUFI270C3Prclm Amd.docx

lupus erythematosus, angina, coronary artery disease, peripheral vascular disease, ulcerative colitis, Crohn's disease, organ rejection, epilepsy, anxiety, degenerative arthritis, vasculitis, and inflammation.

71 (original). The method of claim 57 wherein the detecting is continuous.

72 (original). The method of claim 57 wherein the detecting is periodic.

73 (original). The method of claim 57 wherein at least one therapeutic drug is selected from the group consisting of: α-Hydroxy-Alprazolam; Aceccainide (NAPA); Acetaminophen (Tylenol); Acetylmorphine; Acetylsalicylic Acid (as Salicylates); α-hydroxy-alprazolam; Alprazolam (Xanax); Amantadine (Symmetrel); Ambien (Zolpidem); Amikacin (Amikin); Amiodarone (Cordarone); Amitriptyline (Elavil) & Nortriptyline; Amobarbital (Amytal); Amafranil (Clomipramine) & Desmethylclomipramine; Ativan (Lorazepam); Aventyl (Nortriptyline); Benadryl (Diphenhydramine); Benzodiazepines; Benzoylecgonine; Benztropine (Cogentin); Bupivacaine (Marcaine); Bupropion (Wellbutrin) and Hydroxybupropion; Butabarbital (Butisol); Butalbital (Fiorinal) Carbamazepine (Tegretol); Cardizem (Diltiazem); Carisoprodol (Soma) & Meprobamate; and Celexa (Citalopram & Desmethylcitalopram).

74 (original). The method of claim 57 wherein at least one therapeutic drug is selected from the group consisting of: Celontin (Methsuximide) (as desmethylmethsuximide); Centrax (Prazepam) (as Desmethyldiazepam); Chloramphenicol (Chloromycetin); Chlordiazepoxide; Chlorpromazine (Thorazine); Chlorpropamide (Diabinese); Clonazepam (Klonopin); Clorazepate (Tranxene); Clozapine; Cocaethylene; Codeine; Cogentin (Benztropine); Compazine (Prochlorperazine); Cordarone (Amiodarone); Coumadin (Warfarin); Cyclobenzaprine (Flexeril); Cyclosporine (Sandimmune); Cylert (Pemoline); Dalmane (Flurazepam) & Desalkylflurazepam; Darvoect; Darvon (Propoxyphene) & Norpropoxyphene; Demerol (Meperidine) & Normeperidine; Depakene (Valproic Acid); Depakote (Divalproex) (Measured as Valproic Acid); Desipramine (Norpramin); Desmethyldiazepam; Desyrel (Trazodone); Diazepam &

Desmethyl diazepam; Diazepam (Valium) Desmethyl diazepam; Dieldrin; Digoxin (Lanoxin); Dilantin (Phenytoin); Disopyramide (Norpace); Dolophine (Methadone); Doriden (Glutethimide); Doxepin (Sinequan) and Desmethyl doxepin; Effexor (Venlafaxine); Ephedrine; Equanil (Meprobamate) Ethanol; Ethosuximide (Zarontin); Ethotoin (Peganone); Felbamate (Felbatol); Fentanyl (Innovar); Fioricet; Fipronil; Flunitrazepam (Rohypnol); Fluoxetine (Prozac) & Norsfluoxetine; Fluphenazine (Prolixin); Fluvoxamine (Luvox); Gabapentin (Neurontin); Gamma-Hydroxybutyric Acid (GHB); Garamycin (Gentamicin); Gentamicin (Garamycin); Halazepam (Paxipam); Halcion (Triazolam); Haldol (Haloperidol); Hydrocodone (Hycodan); Hydroxyzine (Vistaril); Ibuprofen (Advil, Motrin, Nuprin, Rufen); Imipramine (Tofranil) and Desipramine; Inderal (Propranolol); Keppra (Levetiracetam); Ketamine; Lamotrigine (Lamictal); Lanoxin (Digoxin); Lidocaine (Xylocaine); Lindane (Gamma-BHC); Lithium; Lopressor (Metoprolol); Lorazepam (Ativan); and Ludomil.

75 (original). The method of claim 57 wherein at least one therapeutic drug is selected from the group consisting of: Maprotiline; Mebaral (Mephobarbital) & Phenobarbital; Mellaril (Thioridazine) & Mesoridazine; Mephénytoin (Mesantoin); Meprobamate (Miltown, Equanil); Mesantoin (Mephénytoin); Mesoridazine (Serentil); Methadone; Methotrexate (Mexate); Methylsuximide (Celontin) (as desmethylsuximide); Mexiletine (Mexitil); Midazolam (Versed); Mirtazapine (Remeron); Mogadone (Nitrazepam); Molindone (Moban); Morphine; Mysoline (Primidone) & Phenobarbital; NAPA & Procainamide (Pronestyl); NAPA (N-Acetyl-Procainamide); Navane (Thiothixene); Nebcin (Tobramycin); Nefazodone (Serzone); Nembutal (Pentobarbital); Nordiazepam; Olanzapine (Zyprexa); Opiates; Orinase (Tolbutamide); Oxazepam (Serax); Oxcarbazepine (Trileptal) as 10-Hydroxyoxcarbazepine; Oxycodone (Percodan); Oxymorphone (Numorphan); Pamelor (Nortriptyline); Paroxetine (Paxil); Paxil (Paroxetine); Paxipam (Halazepam); Peganone (Ethotoin); PEMA (Phenylethylmalonamide); Pentothal (Thiopental); Perphenazine (Trilafon); Phenergan (Promethazine); Phenothiazine; Phentermine; Phenylglyoxylic Acid; Procainamide (Pronestyl) & NAPA; Promazine (Sparine); Propafenone (Rhythmol); Protriptyline (Vivactyl); Pseudoephedrine; Quetiapine (Seroquel); Restoril (Temazepam); Risperdal (Risperidone) and Hydroxyrisperidone; Secobarbital (Seconal);

JAH/UF-270C3 Prelim And doctla

Sertraline (Zoloft) & Desmethylsertraline; Stelazine (Trifluoperazine); Surmontil (Trimipramine); Tocainide (Tonocard); and Topamax (Topiramate).

76 (original). The method of claim 57 wherein said sensor is selected from the group consisting of: metal-insulator-metal ensemble (MIME) sensors, cross-reactive optical microsensor arrays, fluorescent polymer films, surface enhanced raman spectroscopy (SERS), diode lasers, selected ion flow tubes, metal oxide sensors (MOS), bulk acoustic wave (BAW) sensors, colorimetric tubes, infrared spectroscopy, gas chromatography, semiconductive gas sensor technology; mass spectrometers, fluorescent spectrophotometers, conductive polymer gas sensor technology; aptamer sensor technology; amplifying fluorescent polymer (Afp) sensor technology; or surface acoustic wave gas sensor technology.

77 (original). The method of claim 76 wherein the sensor technology produces a unique electronic fingerprint to characterize the detection and concentration of said at least one target marker.

78 (original). The method of claim 57 further comprising the step of recording data from said sensor.

79 (original). The method of claim 57 further comprising the step of transmitting data from said sensor.

80 (original). The method of claim 57 further comprising comparing at least one target marker detected with a predetermined signature profile.

81 (original). The method of claim 57 further comprising capturing a sample of expired gases prior to exposing said sensor to expired gases.

JAUFA270C3\Preflim Amd.doc\la

82 (original). The method of claim 57 further comprising dehumidifying expired gases prior to exposing said sensor to expired gases.

83 (original). The method of claim 57 further comprising exposing said sensor to expired gases during exhalation of the patient's breath.

84 (original). The method of claim 57 further comprising assigning a numerical value to the concentration as analyzed upon reaching a level of anesthetic effect in said patient and, thereafter, assigning higher or lower values to the concentration based on its relative changes.

85 (original). The method of claim 57 wherein said sensor is portable.

86 (original). The method of claim 57 wherein at least one therapeutic drug is a psychiatric drug.

87 (original). The method of claim 86 wherein at least one therapeutic drug is selected from the group consisting of antidepressants, anti-psychotics, anti-anxiety drugs, and depressants.

88 (original). A therapeutic drug delivery and monitoring system for delivering an appropriate dosage of the therapeutic drug to a patient:

at least one therapeutic drug supply having a controller for controlling the amount of therapeutic drug provided by the supply to the patient;

an expired gas sensor for analyzing the patient's breath for the presence and concentration of at least one target marker indicative of therapeutic drug concentrations in the patient's bloodstream, and for sending a signal regarding the concentration of the therapeutic drug in the patient's bloodstream; and

a system controller connected to the therapeutic drug supply, which receives and analyzes the signal from the sensor and controls the amount of therapeutic drug administered to the patient based on the signal.

89 (original). The system of claim 88 wherein the expired gas sensor comprise a sensor for analyzing the gas for concentration of at least one target marker indicative of the therapeutic drug concentration in the patient's bloodstream and a processor for calculating the pharmacodynamic and pharmacokinetic effect of the therapeutic drug based on the concentration of the therapeutic drug.

90 (original). The system of claim 89 wherein the sensor is selected from the group consisting of: metal-insulator-metal ensemble (MIME) sensors, cross-reactive optical microsensor arrays, fluorescent polymer films, surface enhanced raman spectroscopy (SERS), diode lasers; selected ion flow tubes, metal oxide sensors (MOS), bulk acoustic wave (BAW) sensors, colorimetric tubes, infrared spectroscopy, gas chromatography, semiconductive gas sensor technology; mass spectrometers, gluorescent spectrophotometers, conductive polymer gas sensor technology; aptamer sensor technology; amplifying fluorescent polymer (Afp) sensor technology; or surface acoustic wave gas sensor technology.